IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SMITH KLINE & FRENCH LABORATORIES LIMITED and SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	)	Civil Action No. 05-197-GMS

PLAINTIFF GLAXOSMITHKLINE'S POST-TRIAL BRIEF ON THE ISSUE OF INEQUITABLE CONDUCT

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I. INTRODUCTION

Teva's validity challenge to United States Patent No. 4,824,860 ("the '860 patent") was so weak that it prompted a ruling from the bench in GSK's favor at the conclusion of the trial. Teva's inequitable conduct defense is even weaker. In attempting to support its inequitable conduct allegations with respect to the '860 patent, Teva relies almost exclusively on the deposition testimony of fact witnesses that the parties submitted to the Court by designation post-trial. Nothing in this paper record discharges Teva's heavy burden of proving inequitable conduct by clear and convincing evidence. Indeed, Teva's allegations fail at the threshold

The thrust of Teva's inequitable conduct claim is a back-door challenge to the inventorship determination for the '860 patent. Teva lists a variety of people whom it suggests should have been named as inventors – ranging from Annette Wright, a lab technician whom Teva never sought to depose, to Dr. Brenda Costall, a researcher who performed work for GSK under contract, to a GSK patent attorney whom Teva cannot even identify by name. Yet Teva has failed to identify a single witness who even suggested that David Owen was not properly named as the sole inventor on the '860 patent. In fact, the testimony of Dr. Costall and another GSK witness, Dr. Carol Harvey, confirms that it was Dr. Owen and Dr. Owen alone who came up with the idea of using ropinirole to treat Parkinson's Disease.

Should the Court go any further in reaching its decision, there is not a shred of evidence to support a finding that there was an intent to deceive the PTO or any motive to do so. Most notably, the alleged inventors were all employees of GSK or under a duty to assign any inventions to GSK. Accordingly, nothing of consequence turned on whether they were named as inventors. Moreover, while Teva makes much of Dr. Owen's testimony that he relied on GSK patent attorneys to determine inventorship and claim scope, the testimony of Teva's own

witnesses, Ms. Jaskot and Dr. Long, makes clear that this type of reliance is perfectly reasonable when it comes to the preparation of legal documents.

Teva also attempts to cobble together an inequitable conduct claim based on statements in the background section of the '860 patent concerning dopamine receptors and prior art dopamine agonists. But the undisputed evidence, including testimony from Teva's own pharmacology expert, demonstrates that these statements were ***true***. Furthermore, these true statements were made in the background section of the patent and had no bearing on the question of patentability.

GSK has filed proposed findings of fact and conclusions of law that detail the relevant evidence relating to Teva's inequitable conduct defense. This brief summarizes that evidence and responds to the arguments set forth in Teva's [Proposed] Findings of Fact and Conclusions of Law on Teva Pharmaceuticals USA, Inc's Defense and Counterclaim of Inequitable Conduct ("Teva Proposed Inequitable Conduct Findings") [D.I. 184] and accompanying post-trial brief ("Teva Inequitable Conduct Brief") [D.I. 185].

II. TEVA'S ALLEGATIONS

In its Amended Answer and Counterclaim, filed June 28, 2006 and corrected July 10, 2006 ("Amended Complaint") [D.I. 73], Teva was required to plead with particularity its claims of inequitable conduct. *See Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC,* 350 F.3d 1327, 1344 (Fed. Cir. 2003); *see also EMC Corp. v. Storage Tech. Corp.,* 921 F. Supp. 1261, 1263 (D. Del.1996) ("the particularity requirement of Rule 9(b) applies to inequitable conduct charges"). In its Seventh Affirmative Defense, Teva made the following particularized allegations:

(1) that Dr. Owen "never conceived of using any compound other than ropinirole" and that the "nonjoinder of individual(s) responsible for conceiving of portions of the claimed invention(s) covering compounds other than ropinirole [claim 1] . . . was done with the intent to deceive," Amended Complaint ¶ 60;

(2) that Professors Brenda Costall and R.J. Naylor of the University of Bradford in England were the first to conceive of the idea of using ropinirole as an anti-Parkinson's drug, *id.* ¶ 61; and

(3) that the '860 patent "misleadingly states that the anti-Parkinsonian activity of ropinirole and the other claimed compounds is the result of their post-synaptic, rather than pre-synaptic, site of action and that the fact that ropinirole and the other claimed compounds were known to act-pre-synaptically would not lead a person to ordinary skill in the art to conclude that these compounds could be used to treat Parkinson's disease. The '860 patent supported this assertion by mischaracterizing the prior art bromocriptine compound as a "post-synaptic dopamine agonist" in the brain . . . ." *Id.* ¶ 62.

In its post-trial filings, Teva makes several allegations that were never pled in its counterclaim or set forth in the joint pre-trial order in which the parties were required to identify

their respective contentions. Most importantly, for the first time, Teva alleges that a technician working under Dr. Owen's supervision, Annette Wright, should be an inventor and that the failure to name her was an act of inequitable conduct.[1/] This is a particularly reckless allegation by Teva given that it never even took, or even asked for, her deposition, despite the fact that she was disclosed as a knowledgeable witness in October 2005. It should be rejected for a host of reasons, not least because Teva's failure to mention the allegation in its pleadings constitutes a waiver.

III. RELEVANT FACTS[2/]

The '860 patent addresses the use of certain indolone compounds in the treatment of Parkinson's Disease. *See* '860 Patent (PTX 35). The '860 patent is one of a series of patents that GSK obtained relating to indolone compounds, including U.S. Patent No. 4,314,944 ("the '944 patent") and U.S. Patent No. 4,458,808 ("the '808 patent") to ropinirole and other indolone compounds.

The '808 patent describes the claimed compounds as having activity at pre-synaptic peripheral D_2 receptors, *see id.* at Col. 4, ll. 31-44 (PTX 13); GSK Proposed Inequitable Conduct Findings ¶ 16, and utility as dopamine agonists in treating disorders of the cardiovascular system, *see* '808 Patent, Col. 1, ll. 46-48; Col. 4, ll. 26-29 (PTX 13); *see also* GSK Proposed Validity Findings ¶¶ 77-81.

1/ Teva also proposes certain findings regarding the issue of dosage levels for ropinirole. Teva's Proposed Inequitable Conduct Findings ¶ 17. The issue was also never raised with respect to the '860 patent and should be deemed waived.

2/ The facts are set forth in more detail in GSK's Proposed Findings of Fact and Conclusions of Law on Inequitable Conduct ("GSK Proposed Inequitable Conduct Findings").

In the years after ropinirole's discovery, GSK scientists attempted to develop it as a cardiovascular drug. *See* GSK Proposed Inequitable Conduct Findings ¶ 18. In the fall of 1985, development of ropinirole was transferred from GSK's operations in the United States to its facilities in Welwyn, England ("Welwyn"). *See* GSK Proposed Inequitable Conduct Findings ¶ 19. The understanding within GSK at the time was that ropinirole did not have central nervous system ("CNS") effects. *See* GSK Proposed Inequitable Conduct Findings ¶ 20.

Dr. David Owen first became directly involved with the development of ropinirole when the compound was transferred to Welwyn. *See* GSK Proposed Inequitable Conduct Findings ¶ 21. At the time, Dr. Owen was the senior pharmacologist for GSK in the UK and was responsible for a significant number of laboratories.

Upon transfer of ropinirole to Welwyn, Dr. Owen determined that it was necessary to conduct some additional studies for the purpose of understanding the compound. GSK Proposed Inequitable Conduct Findings ¶ 22. More specifically, Dr. Owen decided that it was appropriate to conduct conscious animal cardiovascular measurements of heart rate and blood pressure. *Id.* Those experiments were subsequently performed under Dr. Owen's direction by a laboratory technician, Annette Wright. *Id.* *See* GSK Proposed Inequitable Conduct Findings ¶ 22-23.

In the course of performing the experiments, Ms. Wright observed that there were some behavioral changes in the rats with which she was not familiar. *See* GSK Proposed Inequitable Conduct Findings ¶ 24. She notified Dr. Owen of the changes, and he went to observe the rats at her request. *Id.* The specific behavioral effects that Ms. Wright and Dr. Owen observed included agitation and "stereotypy" (i.e., sniffing behavior). *Id.*; Laboratory Notebook of Annette Wright at GSK-REQ000385-86; 390-91; 395-96 (DTX 24).

Dr. Owen's interpretation of this behavior was that ropinirole had CNS effects. GSK Proposed Inequitable Conduct Findings ¶ 25. His first reaction upon drawing this conclusion was "oh dear, there's a problem here," because CNS effects were undesirable, as a general rule, in compounds targeted for cardiovascular development. *Id.* After his initial reaction of concern, however, Dr. Owen began to see the CNS effects of ropinirole as an advantage and came up with the idea of using ropinirole to treat Parkinson's Disease. GSK Proposed Inequitable Conduct Findings ¶ 26.

To the best of Dr. Owen's recollection, the first time he shared his hypothesis with anyone was in a telephone conversation with Dr. Brenda Costall at the University of Bradford ("Bradford") in the United Kingdom. *See* GSK Proposed Inequitable Conduct Findings ¶ 28. Dr. Costall had developed animal models for studying anti-Parkinson's activities. *See* GSK Proposed Inequitable Conduct Findings ¶ 29. Dr. Owen asked Dr. Costall and her colleagues to test his hypothesis that ropinirole could be used to treat Parkinson's Disease and also to put it into context by determining whether the compound had any other effects on the central nervous system. *See* GSK Proposed Inequitable Conduct Findings ¶ 30. According to Dr. Costall, the work carried out by Bradford "confirmed the hypothesis presented by Dr. Owen that ropinirole had anti-Parkinson's potential." GSK Proposed Inequitable Conduct Findings ¶ 33.

Bradford was compensated for the costs of the animals and for the personnel involved in carrying out the work. *See* GSK Proposed Inequitable Conduct Findings ¶ 35. Consistent with its role on the project, Bradford was contractually required to assign to GSK any intellectual property it developed. *Id.* The Bradford researchers were also required to turn over the results of their work to GSK and were prohibited from publishing information about that work without GSK approval. *Id.*

The priority application for the '860 patent (United Kingdom Patent No. 8712073) was filed on May 21, 1987, and the U.S. patent application was filed on May 19, 1988. *See* '860 Patent (PTX 35). David Owen is named as the sole inventor in the '860 patent application, as well as on the patent. *See* DTX 19 at GSK-REQ000539-554; '860 Patent (PTX 35).

The '860 patent lists two individuals as GSK's patent agents or attorneys: Stuart R. Suter and the Honorable Alan D. Lourie, who was head of GSK's patent department at that time. *See* '860 Patent (PTX 35). Neither is currently employed by GSK, and Teva did not seek to depose them in this action.

Peter Giddings is currently the Head of Patent Administration and Information in GSK's Corporate Intellectual Property Department. *See* GSK Proposed Inequitable Conduct Findings ¶ 44. Dr. Giddings is a U.K. Chartered Patent Agent and a European Patent Attorney. *Id.* He was responsible for drafting the U.K. priority application on which the United States application is based. *Id.* Dr. Giddings testified that he does not remember particular details concerning the preparation of the applications leading to the '860 patent (which occurred almost twenty years ago), including the investigation of inventorship and which documents Dr. Owen reviewed prior to the filing of the UK or US patent applications. *See* GSK Proposed Inequitable Conduct Findings ¶ 45. Dr. Giddings did, however, testify about the general practice he followed at the time with respect to the preparation of patent applications, including his practice of gathering all relevant information to make an inventorship determination. GSK Proposed Inequitable Conduct Findings ¶ 46.

IV. ARGUMENT

A. Teva's Allegations Relating To Inventorship Are Without Merit

1. *Bradford Is Not a Co-Inventor*

Dr. Costall and the other researchers at Bradford University did not participate in the conception of the claimed invention.[3/] Teva's contention that the Bradford researchers should have been named as inventors flies in the face of the undisputed testimony of Dr. Costall herself, who credited Dr. Owen with the idea of using ropinirole to treat Parkinson's disease.

The undisputed testimony of both Dr. Owen and Dr. Costall confirms that Bradford could not have "contribute[d] to the conception of the invention," *Fina Oil* 123 F.3d at 1474, because the conception occurred before Dr. Owen ever spoke to Dr. Costall. In particular, both Dr. Owen and Dr. Costall agree that Dr. Owen *first* conceived of the idea of using ropinirole to treat Parkinson's Disease *and then* commissioned Drs. Costall and Naylor to perform confirmatory tests. Dr. Owen testified:

> Q: So prior to approaching Dr. Costall to do this experimental work, did you have a definite idea that ropinirole could be used to treat Parkinson's, or was that more of a guess?
>
> MS. WIGMORE: Objection.
>
> A: No, it was absolutely in my mind that it could be a treatment for Parkinson's disease, that is a hypothesis that was formed, but I needed others to confirm it, I didn't have the experimental models under my direction to confirm that. I wanted people who if they confirmed it, others would believe them.

GSK Proposed Inequitable Conduct Findings ¶ 31.

3/ In order to be a joint inventor, one "must contribute in some significant manner to the conception of the invention." *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466, 1474 (Fed. Cir. 1997). "Conception is the 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'" *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 Robinson on Patents 532 (1890)).

Dr. Costall's testimony was completely consistent on this point:

> Q: How would you characterize the scope of your and your team's work on ropinirole?
>
> MS. WIGMORE: Objection, vague.
>
> BY MR. BRAHMA:
>
> Q: You can answer.
>
> A: I can start with the initial work, ***which was to confirm the hypothesis that had been formulated at Smith Kline & French that ropinirole may have anti-Parkinsonian potential.***
>
> * * *
>
> Q: Let me ask you, how did you first get involved in doing this research work on ropinirole for Smith Kline?
>
> A: I received a telephone call from Dr. David Owen from Smith Kline & French.
>
> Q: And what did you and Dr. Owen discuss?
>
> A: Dr. Owen described to me some behavioral effects that had occurred whilst observing this compound then known as 101468, ***and he said that in his view, that this represented a compound with anti-Parkinson potential***, and asked whether we would be prepared to collaborate with them in confirming his hypothesis.
>
> Q: Can you tell me approximately when that conversation was?
>
> A: Approximately 1986.

GSK Proposed Inequitable Conduct Findings ¶ 33 (emphasis added).[4/]

Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994) is closely on point. In *Burroughs Wellcome*, the Federal Circuit rejected a claim of joint invention by scientists at the NIH who worked on a project developing AZT, a drug used to treat HIV infection. The claimed invention was to "compositions and methods of using AZT to treat

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[4/] In light of this testimony, Teva's attempt to premise an inequitable conduct claim on 35 U.S.C. § 102(f) is fatally flawed. Section 102(f) provides that a person shall be entitled to a patent unless "he did not himself invent the subject matter sought to be patented." But, Dr. Owen did not get the idea of treating Parkinson's with ropinirole from Bradford; rather, the facts show exactly the opposite.

AIDS." *Id.* at 1230. The Burroughs Wellcome inventors selected AZT as a potential HIV drug based on screening of the drug at Burroughs Wellcome. They then sent AZT to the NIH for further testing in other cell lines and in humans. *Id.* at 1226. The Federal Circuit rejected the claim to inventorship of the NIH scientists on the grounds that they merely confirmed the prior invention of the Burroughs Wellcome inventors. *Id.* at 1230. Although the NIH researchers "exercised considerable skill in conducting the tests," the court found that their work merely "confirmed the operability of the inventions" and demonstrated "that the Burroughs Wellcome inventors had a definite and permanent idea of the inventions." *Id.* Accordingly, the testing "was part of the reduction to practice and inured to the benefit of Burroughs Wellcome." *Id.*; *see also id.* at 1228 ("[A]n inventor need not know that his invention will work for conception to be complete. He need only show that he had the idea; the discovery that an invention actually works is part of its reduction to practice.").[5/] Bradford, like the NIH researchers in *Burroughs Wellcome*, simply performed testing at the request of the inventor to confirm activity. Bradford's tests merely "confirmed the operability of the inventions" and demonstrated that Dr. Owen "had a definite and permanent idea of the inventions." *Id.* at 1230. Accordingly, the testing "was part of the reduction to practice and inured to the benefit of" Dr. Owen. *Id.*[6/]

[5/] *Burroughs Wellcome* also eviscerates Teva's attempt to suggest that because Dr. Owen did not select the particular tests at issue, Bradford must be the inventor. *See* Teva Proposed Inequitable Conduct Findings ¶ 80. In *Burroughs Wellcome*, the referring inventor "hardly controlled the conduct of the testing, which necessarily involved interpretation of results for which [the NIH researchers], and very few others, were uniquely qualified." 40 F.3d at 1230. Nevertheless, the Federal Circuit found that the referring inventor—not the researchers who performed the testing—was the inventor. In any case, unlike the NIH researchers in *Burroughs Wellcome*, no one from Bradford is even claiming to be an inventor.

[6/] One does not become a co-inventor by "simply reduc[ing] the inventor's idea to practice." *Ethicon Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998) (citations omitted); *see also Burroughs Wellcome*, 40 F.3d at 1230.

Teva's attempt to distinguish *Burroughs Wellcome* on the basis that a draft patent application had been prepared by the Burroughs Wellcome inventors is unavailing. The draft's importance in *Burroughs Wellcome* was as corroboration; here, corroboration is supplied by at least two witnesses: Dr. Carol Harvey, who headed the ropinirole project at GSK when it was transferred to England, and Dr. Costall herself.[7/] GSK Proposed Inequitable Conduct Findings ¶¶ 32-33.

Teva's claim that there is a conflict between GSK's position on obviousness and Dr. Owen's status as an inventor is also wrong. According to Teva, "GSK contended that merely knowing that a compound was a centrally acting D_2 agonist was not enough to give a person of ordinary skill in the relevant field a reasonable expectation that the compound was a potential anti-Parkinson's agent . . . . Yet this was the only thing that Dr. Owen claims to have contributed to the inventions claimed in the '860 patent." Teva Inequitable Conduct Brief at 26. This purported conflict fatally confuses the inventor with a person of ordinary skill.[8/]

[7/] Teva is wrong in suggesting that written corroboration is necessary to prove conception. *See, e.g., Sandt Tech., Ltd. v. Resco Metal & Plastics Corp.*, 264 F.3d 1344, 1351 (Fed. Cir. 2001) ("oral testimony of someone other than the alleged inventor may corroborate an inventor's testimony") (citation omitted); *Bell Telephone Labs, Inc. v. Hughes Aircraft Co.*, 564 F.2d 654, 657 (3d Cir. 1977) ("[T]he corroborating evidence need not take any particular form, but may be either documentary or oral.") (citations omitted). More importantly, however, corroboration is not relevant to the issues in this case at all, because there is no claim by Teva to invalidate the patent based on improper inventorship. Its claim is limited to the issue of inequitable conduct and the allegation that Dr. Owen deliberately misled the Patent Office in claiming to be the sole inventor of the '860 patent, for which there is absolutely no support in the record.

[8/] The Federal Circuit has noted repeatedly that the knowledge of an inventor may not be substituted for the knowledge of one of ordinary skill in the art. *See Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (noting that the "actual inventor's skill is irrelevant" to the obviousness inquiry, which requires a determination of the scope and content of the prior art); *Bausch & Lomb, Inc. v. Barnes-Hing/Hydrocurve, Inc.*, 796 F.2d 443, 447-48 (Fed. Cir. 1986) (same).

First, Dr. Owen's "contribution" to the invention was the invention itself – the idea to use ropinirole as a Parkinson's drug – not simply that it was a centrally acting D_2 agonist. Second, persons skilled in the art did not appreciate that ropinirole was centrally acting; it was thought to be peripherally acting. *See* GSK Proposed Inequitable Conduct Findings ¶ 20.[9/] And, while a person of ordinary skill in the art could not conclude that a compound was a potential anti-Parkinson's agent based solely on knowledge that it was a centrally acting D_2 agonist, that fact has nothing to do with Dr. Owen's entitlement to a patent. Insight beyond those of ordinary skill is the essence of invention.

Finally, the issue Teva has chosen to present to the Court is not inventorship but inequitable conduct, and on that issue Teva's proof has utterly failed for lack of evidence of deceptive intent. Dr. Costall's testimony alone is sufficient to defeat Teva's inequitable conduct claim. "When an alleged omitted co-inventor does not claim to be such, it can hardly be inequitable conduct not to identify that person to the PTO as an inventor." *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1576 (Fed. Cir. 1996). Equally fatal to Teva's claim is the absence of any conceivable motive for deceiving the PTO. It is undisputed that, consistent with its role on the project, Bradford had a duty to assign any inventive work to GSK. GSK Proposed Inequitable Conduct Findings ¶ 35. Teva's speculation that "[i]f the University of Bradford professors were the real inventors, then GSK may not have exclusive rights, or

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9/ Indeed, a 1985 publication by Gregory Gallagher (the named inventor of the '808 patent) and others describes a number of tests conducted on ropinirole and concludes: "These results indicate that 1(c) [ropinirole] *does not produce the central behavioral effects often seen with dopamine agonists*." Gallagher, Jr., G., et al., *4-[2-(Di-n-propylamino)ethyl]-2(3H)-indolone: A Prejunctional Dopamine Receptor Agonist,* J. Med. Chem., 28, 1533, 1535 (1985) ("the 1985 Gallagher article") (PTX 17) (emphasis added).

potentially any rights, to the use of ropinirole to treat Parkinson's disease" has no basis in the record. Teva Inequitable Conduct Brief at 32.

2. *Ms. Wright Was Not A Co-Inventor*

As indicated above, a claim of inequitable conduct based on the failure to join Annette Wright as an inventor has been waived. Even if it is considered on the merits, this claim is baseless.

Teva states rhetorically that "if the 'invention' of the '860 patent is the discovery that ropinirole acts centrally, Ms. Wright, not Dr. Owen, is a proper co-inventor, if not the sole inventor." Teva Inequitable Conduct Brief at 28. But, as is true in all areas of patent law, for purposes of inventorship, the invention is ***what is claimed.*** *E.g., Trovan, Ltd. v. Sokymat SA, Irori,* 299 F.3d 1292, 1302 (Fed. Cir. 2002) ("an inventorship analysis, like an infringement or invalidity analysis, begins as a first step with a construction of each asserted claim to determine the subject matter encompassed thereby"). There is no evidence that Ms. Wright had any conception whatsoever of the claimed invention – the use of ropinirole to treat Parkinson's Disease. Indeed, there is no evidence from Ms. Wright at all. Teva never deposed her.

What evidence there is of Ms. Wright's role comes from Dr. Owen and Mr. Eden. According to their undisputed testimony, Ms. Wright was a technician who performed experiments at Dr. Owen's direction and reported her observations. She did not suggest the use of ropinirole to treat Parkinson's. Her contribution at most was to follow Dr. Owen's direction to run certain experiments that led her to observe stereotypy in rats, which Dr. Owen then observed himself and relied on in arriving at his invention. Contributions such as this do not rise to the level of invention. *See, e.g., Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1380-81 (Fed. Cir. 2001) (rejecting machinist's claim to joint inventorship given that he did no more than follow the actual inventor's instructions to insert fixation means in a spinal implant,

which required only the exercise of the normal skills expected of an ordinary machinist); *see also, Mueller Brass Co. v. Reading Indus.*, 352 F. Supp. 1357, 1373 (E.D. Pa., 1972), *aff'd* 487 F.2d 1395 (3d Cir. 1973) ("[A] lab technician who carried out a certain experiment under instructions of his superiors, recorded the results, and moved on to other things . . . was not a co-inventor of the claimed method.").

Finally, as with Teva's contentions concerning Bradford, even if a legitimate question of inventorship had been raised,[10/] there is no basis whatsoever for a finding of inequitable conduct. The issue of joint inventorship has been called "one of the muddiest concepts in the muddy metaphysics of the patent law." *Mueller Brass Co.*, 352 F. Supp. at 1372. As was completely proper, Dr. Owen relied on his attorneys to apply this difficult concept to the available facts and determine inventorship. GSK Proposed Inequitable Conduct Findings ¶ 78. There is not a scrap of evidence that Judge Lourie, Mr. Suter or Dr. Giddings exercised anything but good faith in making their determination. Accordingly, there is no basis for rendering the '860 patent unenforceable based on any alleged conduct with respect to inventorship.

3. *The Generic Claim Of The '860 Patent Does Not Raise An Inventorship Issue*

Like virtually all patents directed to chemical compounds or their use, the '860 patent includes a claim to a generic formula (claim 1) that covers more than the chemical compound that was used by the named inventor. As the Court is no doubt aware, such generic claims

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10/ In truth, there is no such legitimate issue. The named inventors on an issued patent are presumed to be the true and only inventors. *Hess v. Adv. Cardiovascular Sys., Inc.*, 106 F.3d 976, 980 (Fed. Cir. 1997), *cert. denied*, 520 U.S. 1277, 117 S. Ct. 2459 (1997). "Any party wishing to challenge the . . . patent's current inventorship must ultimately come forward with clear and convincing evidence of facts that support its contentions." *Fina Oil & Chem. Co.*, 123 F.3d at 1474 (citing *Hess*, 106 F.3d at 979-80). Teva's proof falls short of this exacting standard. And even if Teva could demonstrate an error in inventorship, the remedy would not be unenforceability but, instead, would be correction of the patent under 35 U.S.C. § 256.

routinely spawn defenses under the enablement or written description requirements based on the allegation that the claims are unreasonably broad. *See, e.g., Ortho-McNeil Pharm., Inc. v. Mylan Labs, Inc.*, Nos. 04-1689, 06-757, 2006 WL 2865469, at *2 (D.N.J. Oct. 5, 2006) (granting summary judgment motion in favor of plaintiff because there was no genuine issue of material fact over whether the generic claim met the requirements of enablement under 35 U.S.C. § 112). Here, GSK dropped claim 1 well before trial, so there is no reason to consider its validity under 35 U.S.C. § 112. Nonetheless, Teva has sought to transform a commonplace defense of undue claim breadth into an unsupported defense of inequitable conduct based on improper inventorship.

Although it casts this defense as an inventorship argument, Teva does not even purport to identify who the "unnamed" inventors are. Teva cites no case, and we have located none, where a court has found improper inventorship in the absence of an identification of the true inventors. Instead, Teva's pursuit of this defense ignores its heavy burden and depends on an explicit and erroneous attempt to shift the burden of proof to GSK. *See, e.g.,* Teva Inequitable Conduct Brief at 29 ("Indeed, GSK has been unable or unwilling to reveal that information to this day.").

In truth, moreover, there is no mystery about the inventorship of claim 1. Dr. Owen is presumed to be its inventor and was entitled to claim its scope based on his work with ropinirole. Teva's inequitable conduct defense based on claim 1 rests on a basic misunderstanding of what it takes to claim a generic formula and the manner in which patent claims are drafted.

In particular, there is no rule limiting patents to the precise product or method developed by an inventor. Patents routinely seek protection going beyond the specific work of the named inventor. If such protection could not be obtained, the value of patents would be severely compromised. The understood role of the patent attorney is to obtain claims as broad as possible

under the patent statute consistent with what is described in the patent specification. *See, e.g.*, Robert C. Faber, *Landis on Mechanics of Patent Claim Drafting*. § 10:1.1 (5th ed. 2005) ("Broad coverage means not only that every particular preferred disclosed embodiment is protected in the claims, but that the claims cover all expected and unanticipated equivalents that competitors and others may later develop and all intentional and unintentional copies of the claimed invention which embody the inventor's concept . . . . It is the claim drafter's job to have written the claims in the application to not only cover what the attorney and the inventor/client could at the time of application prosecution have envisioned as competing products, but to cover competitive products which neither the inventor nor the attorney thought of or could even have imagined at the time, but which employ the concept of the invention."); Jeffrey G. Sheldon, *How to Write a Patent Application*, Practicing Law Institute, § 6.5.3 (2006) ("The broadest claim should be as broad as possible in view of the prior art. As long as the broad claim is not anticipated by art known to the inventor, it cannot hurt to ask for the broad claim. At worst, the examiner will not allow the broadest claims. Thus, it is recommended that the practitioner be greedy when initially writing the application."); Irving Kayton, *Kayton on Patents*, 3-1 (2d ed. 1983) ("During the prosecution stage the drafter will naturally attempt to write one claim that is as broad as the prior art of which he is aware will permit and that is supported by the disclosure in his patent application.").

In seeking such claims, patent lawyers are guided by well-established principles concerning when an inventor is entitled to a generic claim. For example,

- The scope of enablement must only bear a "reasonable correlation" to the scope of the claims. *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. *In re Fisher*, 427 F.2d at 839.

- "Although one may envision a general concept, what one usually does first in making or isolating a chemical or chemical-related invention is to obtain a specific material or materials. One then broadens the concept to extend it as far as one envisions that other materials will have the same utility and can be similarly made. That broadened concept becomes the genus in a patent application that is both the broadest statement constituting a written description and usually claim 1." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 974 (Fed. Cir. 2002) (Lourie, J., concurring in decision to deny rehearing *en banc*).

- The number and variety of examples are irrelevant if the disclosure is "enabling" and sets forth the "best mode contemplated." *In re Borkowski*, 422 F.2d 904, 953 (C.C.P.A. 1970). A disclosure is enabling even if a considerable amount of experimentation is involved, if it is merely routine. *Ex parte Forman*, 230 USPQ 546 (B.P.A.I. 1986).

- "The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure, even though it is a factor to be considered along with all the other factors." MPEP § 2164.02 at 2100-195 (8th ed., rev. Oct. 2005).

- The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

- Every species need not be described in order that a generic claim meet the written description requirement. "A specification may, within the meaning of 35 U.S.C. §112 ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses." *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988).

In short, upon the discovery of ropinirole, Dr. Owen was entitled to a claim commensurate with the scope of his discovery, without regard to how many embodiments of the invention Dr. Owen worked with or whether some of the embodiments within a generic claim might be inoperative. A patent attorney at GSK drafted an appropriately broad claim and prosecuted it with success in the PTO. This utterly ordinary process of obtaining patent protection does not lead to an inference that there was some unnamed inventor responsible for the generic claim, much less does it support a plausible claim of inequitable conduct. Instead,

the facts surrounding the patenting of Dr. Owen's invention reflect the way patent protection is routinely obtained.

Nothing in the testimony Teva cited supports a contrary conclusion. When Dr. Owen made his discovery, he appropriately left to the GSK patent department the issue of the scope of the claims to seek. GSK Proposed Inequitable Conduct Findings ¶ 81. Naturally enough in light of the nature of the invention and the prior art (which included the '808 patent and the '944 patent that preceded it), the application for the '860 patent presented claims that generally correspond to the compounds described in the '808 patent for use as an anti-Parkinson's treatment. *See* GSK Proposed Inequitable Conduct Findings ¶ 61. Notwithstanding the lack of an express disclosure of test results using specific compounds other than ropinirole, the PTO agreed that Dr. Owen was entitled to claim 1 and issued the patent. Teva has no evidence that Dr. Owen did anything other than what inventors routinely do – describe the invention to patent agents or lawyers and rely on them to obtain claims as broad as permissible in light of what the inventor did. GSK Proposed Inequitable Conduct Findings ¶ 81.

The testimony of Teva's own witnesses at trial makes clear that Dr. Owen's reliance on the GSK patent department to determine the appropriate claim scope and make determinations concerning inventorship was entirely reasonable. Teva's corporate representative, Deborah Jaskot, acknowledged that she similarly relied on lawyers when she executed the Paragraph IV certification that prompted this lawsuit and that she personally did not even read the patents that she certified were invalid, unenforceable, or not infringed. GSK Proposed Inequitable Conduct Findings ¶ 81. Similarly, Teva's pharmacology expert, Dr. Long, acknowledged that he was a named inventor on patents containing genus claims and that he had no idea how the specific claims came to be but, instead, relied on others. *Id.*

In its effort to impugn the integrity of Dr. Owen and GSK's representatives by alleging deceptive intent, Teva relies on factually inaccurate statements and completely twisted logic. According to Teva, if the unspecified inventor of claim 1 had been named, "GSK would have had to disclose additional information, including prior art." Teva Inequitable Conduct Brief at 33. Given that Teva is unable to identify who this unspecified inventor is, that statement is necessarily without support in the record. Teva then says, in a *non-sequitur*, that Dr. Costall (who even Teva does not claim had anything to do with drafting the generic claim) published an article suggesting that several compounds coming within the scope of claim 1 could not be used to treat Parkinson's Disease. But that article did not address indolone compounds coming within claim 1 at all. GSK Proposed Inequitable Conduct Findings ¶ 64.[11/] Rather, the article addresses dopamine derivatives, which is a different class of compounds from the indolones claimed in the '860 patent. *Id.* As GSK's pharmacology expert, Dr. Jenner, made clear at trial, the 1978 Cannon Article, on which Dr. Costall is a co-author, reveals nothing about the activity of indolones because it addresses a different class of compounds altogether:

> Q: Dr. Jenner, as of 1987, what, if anything, could one of ordinary skill in the art have concluded from this article [DTX 160] about the activity of ropinirole hydrochloride?
>
> A: ***I think one of ordinary skill in the art would not have been able to conclude anything because this is a paper dealing with n,n-disubstituted dopamine derivatives. It is not a paper dealing with indolone derivatives. And I think as we've now already established, you cannot make jumps from one class to another when considering these structure activity relationships.***

GSK Proposed Inequitable Conduct Findings ¶ 64 (emphasis added).

[11/] Teva never adduced any evidence of Dr. Costall's views of the relationship, if any, between this article and the indolone compounds in the '860 patent because Teva never inquired about it during her deposition.

Finally, even if this article addressed indolones, GSK's attorneys would have had to have known about the article themselves in order to hatch the plot not to name her as an inventor for the purpose of concealing the article. But, of course, if they knew about the article, they could not have been able to skirt a duty of disclosure by omitting Dr. Costall as an inventor, and there is no evidence whatsoever that they knew about the article.[12/]

B. GSK's Statements Regarding Pre-Synaptic and Post-Synaptic Activity Were True And Cannot Form the Basis for a Finding of Inequitable Conduct

Teva's logic in making a claim of inequitable conduct based on the '860 patent's characterization of a prior art compound, bromocriptine, is equally meritless. That characterization was indisputably true, as conceded by Teva's own expert, and therefore cannot conceivably support a claim of inequitable conduct.

According to Teva, the '860 patent was false and misleading in describing bromocriptine as post-synaptic dopamine agonist. The background section of the '860 patent contains the

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12/ Teva also claims that another compound within the genus, "Compound 31" in DeMarinis, et al., *Syntheses and in Vitro Evaluation of 4-(2-Aminoethyl)-2(3H)-indolones and Related Compounds as Peripheral Prejunctional Dopamine Receptor Agonists*, J. Med. Chem., 929, 939-47 (1986) (the "1986 DeMarinis article") (DTX 56), would be inactive. This argument is incorrect for the reasons identified in GSK Proposed Inequitable Conduct Findings ¶¶ 69-73.

Further, Teva's suggestion that the presence of a small number of allegedly inactive compounds within the genus is either invalidating for reason of deception is unfounded. Rather, "[i]t is not a function of the claims to specifically exclude . . . possible inoperative substances . . . ." *Atlas Powder Co.*, 750 F.2d at 1576 (quoting *In re Dinh-Nguyen,* 492 F.2d 856, 858-59 (C.C.P.A. 1974)). Potentially inoperative species are only non-enabling "if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention." *Id.* (citing *In re Cook,* 439 F.2d 730, 735 (1971)). Thus, Teva's argument that one would expect inactivity from certain compounds within the genus is not an invalidity argument, Teva Proposed Inequitable Conduct Findings ¶¶ 103-05—if one would *expect* that inactivity, one would not need to "experiment unduly" to practice the invention. *Atlas Powder Co.*, 750 F.2d at 1576 (citing *In re Cook,* 439 F.2d at 735).

following statement concerning prior art treatments for Parkinson's Disease, including bromocriptine:

> An alternative form of therapy is to administer post-synaptic dopamine agonists, for example ergot alkaloids such as bromocriptine—however, this approach is also associated with side-effects. For example, patients receiving bromocriptine often experience dyskinesia[,] psychiatric problems, and in a small number of cases experience vasopastic phenomena and angina. In addition bromocriptine also causes psychiatric side-effects such as hallucinations.

'860 Patent, Col. 1, ll.36-44 (PTX 35).

During cross-examination at trial, Teva's pharmacology expert, Dr. Long, conceded that this statement was true:

> Q. So the statement in the patent that bromocriptine is post-synaptic and leads to what could be severe side effects was true; correct?
>
> A. Correct.

GSK Proposed Inequitable Conduct Findings ¶ 99. *See also id.* (agreeing "100 percent" with the statement in the '860 patent that bromocriptine acts post-synaptically).

Teva's suggestion that this indisputably true statement is at odds with the 1986 DeMarinis article (DTX 56) is irrelevant and incorrect. First and foremost, because the statement is ***true*** (as Teva's own expert admits) it cannot be a material misrepresentation and any inconsistency would be irrelevant. Second, there is no inconsistency. The 1986 DeMarinis article focuses solely on *peripheral* dopamine agonist activity, whereas the '860 patent and the statement at issue deal with *central* dopamine agonist activity. The specific statement in the 1986 DeMarinis article that Teva claims is inconsistent with statement about bromocriptine in the '860 patent reads as follows:

> A number of different chemical structures have demonstrated ***preferential agonist activity at peripheral prejunctional D_2 vis-a-vis postjunctional D1 receptors. These include for example***

> alkylated derivatives of dopamine such as di-n-propyldopamine and n-propyl-n-butyldopamine; cyclized dopamine derivatives of the 2-aminotetralin series and apomorphine; ***ergot alkaloids such as bromocryptine*** [sic] and its simplified derivatives like LY 141865.

1986 DeMarinis article at 940 (DTX 56) (emphasis added). This statement, on its face, compares the activity of bromocriptine at *peripheral* D_2 receptors to its activity at *post-junctional* D_1 receptors. The article says absolutely nothing about bromocriptine's activity, or lack thereof, at post-synaptic D_2 receptors (centrally or peripherally).

Teva's expert, Dr. Long, agreed on this point, as well:

> Q: Now, the article is talking only about post-junctional D1 receptors; correct?
>
> A: Well, that's what it says.
>
> Q: Right. And when you testified to His Honor about this yesterday, we didn't look at the first portion of the article that tells us what they're [comparing]. They're comparing the peripheral pre-junctional D2 with the post-junctional D1; correct?
>
> A: That's what they say.
>
> ***Q: Right. And there's nothing in the article that says bromocriptine is not post-synaptic; correct?***
>
> ***A: Right.***

GSK Proposed Inequitable Conduct Findings ¶ 102 (emphasis added).

Furthermore, nothing in the patent or its prosecution supports the proposition that whether bromocriptine was or was not "post-synaptic" would have been material to the prosecution of the '860 patent. As discussed in detail in paragraphs 70 through 73 of GSK Proposed Validity Findings, the fact that a given compound had activity at both pre-synaptic *peripheral* receptors and post-synaptic *central* receptors would not have enabled one of ordinary skill in the art to make any prediction about whether ropinirole would behave similarly. It was believed at the time that there were also compounds that interacted with pre-synaptic peripheral D_2 receptors *but not* post-synaptic central D_2 receptors. GSK Proposed Inequitable Conduct

Findings ¶ 107. In particular, as Dr. Jenner made clear in his testimony, because bromocriptine is part of a different chemical series than the indolone compounds claimed in the '860 patent, one of ordinary skill in the art could not form any view about ropinirole's activity at dopamine receptors based on that of bromocriptine:

> Q: What would one of ordinary skill in the art have known in May of 1987 about bromocriptine's interaction with dopamine receptors?
>
> A: Bromocriptine was known to interact with both pre-synaptic and post-synaptic dopamine receptors in the peripheral and central nervous systems.
>
> * * *
>
> Q: What if anything would one of ordinary skill in the art have concluded about ropinirole's activity at dopamine receptors based on this knowledge about bromocriptine as of May of 1987?
>
> A: Well, I don't think one would have concluded anything, quite frankly, because ropinirole is an indolone compound, bromocriptine is a complex ergot derivative. And I think, as we have heard, and certainly as Drs. Cannon and Long have [taught], you cannot transpose information between one chemical class of dopamine agonists and another.

GSK Proposed Inequitable Conduct Findings ¶ 108. *See also* GSK Proposed Inequitable Conduct Findings ¶ 66; 1986 Cannon article at 173 (DTX 179).

The lack of materiality of the characterization of bromocriptine is also demonstrated by the fact that, during prosecution of the European counterpart to the '860 patent when the alleged error was drawn to GSK's attention, the description of bromocriptine was changed without incident and the European patent issued. *See* Response to European Patent Office Communication at GSK-REQ018298-299, ¶ 3 (Nov. 25, 1991) (DTX 133).[13/] The change of the

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[13/] The application was granted. GSK Proposed Inequitable Conduct Findings ¶ 109. The correspondence identifies an "inadvertent error" in the description of bromocriptine in the European patent application relating to the '860 patent, and states "it is correct to state that bromocriptine is a prejunctional D_2 receptor agonist." *See* DTX 133 at GSK-REQ018298. The

description of bromocriptine in Europe further rebuts any suggestions of an intent to deceive the patent office. Instead, GSK's prompt correction of the alleged error when it was brought to its attention in Europe belies any suggestion that it purposely made an erroneous statement in the application when it was filed.

V. CONCLUSION

Each of Teva's inequitable conduct allegations flies in the face of the facts, the law, and in some instances common sense. Indeed, Teva's claims represent exactly the "plague" on the patent system that the Federal Circuit has condemned. *See Burlington Indus. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988) ("[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague."). The Court should enter judgment declaring the '860 patent valid, infringed and enforceable.

Respectfully submitted,

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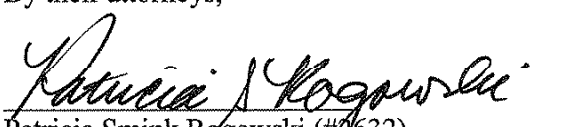
By their attorneys,



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'860 patent, however, does not say anything about bromocriptine's prejunctional (or presynaptic activity); it simply states that bromocriptine is a post-synaptic receptor which, as explained above, is indisputably true. Dr. Giddings acknowledged during his deposition that, notwithstanding his statement in the letter to the EPO, he did not see any contradiction between the 1986 DeMarinis article and the portion of the '860 patent specification relating to bromocriptine. GSK Proposed Inequitable Conduct Findings ¶ 104.

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Dated: March 7, 2007

CERTIFICATE OF SERVICE

I, Patricia Smink Rogowski, hereby certify that on March 7, 2007 **PLAINTIFF GLAXOSMITHKLINE'S POST-TRIAL BRIEF ON THE ISSUE OF INEQUITABLE CONDUCT** was filed with the Court Clerk using CM/ECF which will send notification of such filing(s) to Josy W. Ingersoll.

I hereby further certify that on March 7, 2007, I have also served this document on the attorneys of record at the following addresses as indicated:

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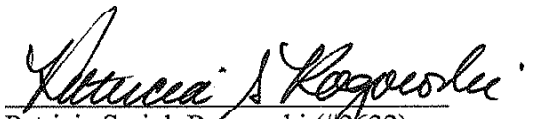

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